

must be cleared of the formaldehyde gas (a small room with nonporous surfaces and no materials or equipment in the room can be cleared of all detectable formaldehyde by aeration for one hour, while larger areas with equipment in them may take a full day). Before formaldehyde is used as a space disinfectant, the area to be treated must be surveyed to ensure that there are no open containers of any acidic solution containing chloride ion in order to prevent the possible formation of bis (chloromethyl) ether, a human carcinogen. Specific OSHA requirements for posting of rooms and equipment, personnel protection, and other requirements are found in 29 CFR 1910.1048.

(2) *Ethylene oxide (EtO)*. EtO sterilization will only be conducted in a sterilizer designed for that purpose and designed to maintain potential exposure levels below the current OSHA standard. EtO is effective against all microorganisms, including spores, molds, pathogenic fungi, and highly resistant thermophilic bacteria. All materials to be used in contact with human skin (for example, clothing, shoes, masks, adhesive tape) must be aerated for at least 24 hours after sterilization and prior to use. Concentrations of 500 to 1000 ppm are required for sterilization. Specific OSHA requirements for the use of ethylene oxide are found in 29 CFR 1910.1047.

(f) *UV Radiation*. UV radiation at a wave length of 253.7 nanometers is a practical method for inactivating airborne viruses, mycoplasma, bacteria, and fungi. The usefulness of UV radiation on exposed surfaces is limited by its low penetrating power. UV radiation shall only be relied upon to sterilize surfaces when conventional methods, such as autoclaving or the use of liquid disinfectants, would make the product unusable. An example is data sheets that must be brought out of a biocontainment facility. The UV intensity must be at least 40 microwatts/cm<sup>3</sup> on the surface to be treated. Single sheets of paper may be treated by exposing them to this radiation for a minimum of 15 minutes. A calibrated photoelectric UV intensity meter, capable of measuring UV radiation at a wave length of 253.7 nanometers, will be used whenever a new UV source is

installed, and quarterly thereafter, to ensure the UV source is providing at least 40 microwatts/cm<sup>3</sup> at the work surface. Bulbs should be cleaned routinely to remove any accumulated dust and prolong bulb performance and assure proper energy output. Protective eye wear and clothing may be necessary when working around UV radiation.

#### § 627.34 Disposal.

Inactivation is the first step in the disposal of etiologic agents or materials that are potentially contaminated with them. All contaminated or potentially contaminated materials must be effectively disinfected or sterilized by an approved procedure discussed in § 627.33. After decontamination, reusable items, such as clothing or glassware, may be washed with other uncontaminated or decontaminated items.

(a) *Combustible items*. Combustible disposable items should be bagged and incinerated in an appropriate approved incinerator or otherwise disposed of in accordance with State and local regulations.

(b) *Noncombustible disposable items*. Items will be packaged as stated in § 626.34(e) and disposed of by a licensed waste hauler.

(c) *Equipment*. Equipment that cannot be autoclaved will be decontaminated by gaseous sterilization or with a suitable liquid disinfectant. Such equipment will be certified as decontaminated by the safety officer.

(d) *Waste*. Materials generated, such as solvents, acids, chemical carcinogens, radioactive isotopes, medical waste, or dead animals must be decontaminated, packaged, and then disposed of in accordance with EPA, NRC, local, State, and Federal regulations.

(e) *Mixed waste*. When two or more hazardous materials are mixed together, the mixture will be decontaminated and disposed of in accordance with EPA, NRC, State, and Federal regulations for the mixture, or for the most hazardous material.

(f) *Packaging*. Solid waste will be placed in cans, sturdy bags, or boxes. Rigid, puncture-resistant, sealable containers will be used for packaging "sharps." When wet materials are

packaged for disposal, the materials will be placed in a leak-proof container. Heavy waste will be placed in rigid containers ensuring that the burst strength of the container is not exceeded.

(g) *Labeling.* A method of verifying that all items prepared for disposal have been decontaminated will be established for etiologic agent wastes. Mixed waste will be labeled as appropriate to indicate the hazards that must be addressed after decontamination.

(h) *Recordkeeping.* A manifest will be initiated and maintained, where required, to record the disposition and transfer of waste. Applicable Federal, State, and local ordinances will be followed.

## Subpart F—Importation, Shipment, and Transport of Etiologic Agents

### § 627.35 Introduction.

The CDC of the Public Health Service (PHS), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Department of Transportation (DOT), the United States Postal Service and the International Air Transport Association (IATA) regulate the importation, shipment, and transportation of etiologic agents. This chapter outlines the minimum administrative requirements the commander or institute director are to follow and gives sources for information on the requirements for importation, packaging, labeling, and shipment of etiologic agents.

### § 627.36 Administration.

The commander or institute director will establish the following controls to ensure that etiologic agents are transported with proper authorization, controls, and procedures:

(a) Institute policies will be established in writing to ensure that before etiologic agents are acquired or shipped—

(1) The division chief responsible for the area where work with etiologic agents is to be conducted approves all acquisitions or shipments.

(2) The safety officer is informed in writing of the type and amount of any BL-4 or USDA-restricted etiologic

agent (listed in HHS publication No. (NIH) 88-8395 or current edition) being received, and the estimated date of arrival.

(3) The recipient of all etiologic agents shipped from an institute will be documented.

(4) The commander or institute director approves all acquisitions and shipments of BL-4 or USDA-restricted etiologic agents.

(5) The commander or institute director approves all requests for shipments to or from foreign countries and to individuals not affiliated with an institution or agency (for example, physicians in private practice).

(6) The Office of The Surgeon General, United States Army, or the Commander, United States Army Materiel Command (AMC) approves the initial acquisition and use of all reference stocks of etiologic agents and transfers between Army RDTE activities in accordance with AR 70-65.

(7) There is full compliance with the regulatory requirements referenced in §§ 627.37, 627.38, 627.39 and 627.40.

(8) The following information regarding the recipient and the intended use of BL-4 and USDA-restricted animal pathogens, will be kept on file for 10 years. This information will also be kept for all shipments to or from foreign countries and to individuals not affiliated with an institution or agency (for example, physicians in private practice).

(i) The requester's name and address.

(ii) The type and amount of the etiologic agent to be sent.

(iii) The qualifications of the recipient of the etiologic agent.

(iv) The intended use of the etiologic agent.

(v) A statement indicating that the agent is not for human use.

(b) Etiologic agents assigned to bio-safety level 1, 2, or 3, approved for shipment, and properly labeled and packaged may be shipped by commercial cargo carriers.

(c) All etiologic agents assigned to BL-4 or USDA-restricted animal pathogens approved for shipment and properly packaged, will be accompanied by a designated courier, or under close supervision of a responsible party who will monitor aspects of the shipment,